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## REMARKS

Claims 1-3, 5, 6, 8, 9, 11, 14, 16, 17, 38-43, 45, 48-51, and 58-59 have been allowed and claims 4, 7, 10, 12, 13, 15, 18-37, 44, 46, 47, 52-57, and 60 have been rejected. As set forth above, claims 4, 10, 11, 13, 18-25, 27, 29-32, 34-37, 44, 45, and 47 have now been amended; claims 12, 15, 46, 52-57, and 60 have been canceled; and new claims 61-66 have been added. Therefore upon entry of this amendment, claims 1-11, 13, 14, 16-45, 47-51, 58, 59, and 61-66 will be pending. Entry of the amendments and favorable consideration of the claims are respectfully requested.

### Specification

Per the Examiner's suggestion, the title has been amended to delete the word "NOVEL".

### Claim Rejections – 35 USC § 112, first paragraph (enablement)

Claims 18-37, 52-57 and 60 have been rejected under 35 USC § 112, first paragraph, on the grounds that they contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This basis for this rejection is the alleged unpredictability of gene therapy. Furthermore, on page 6 of the Office Action, the Examiner states that the claimed vector composition comprising therapeutic genes are included in this rejection because the only disclosed use for these vectors is for gene therapy.

Applicant respectfully traverses and asserts that the claimed recombinant adenoviral vectors have uses that are well known in the art other than for gene therapy. For instance, the claimed vectors can be used to transform cells *in vitro* to express proteins of interest and/or to study the effects of heterologous coding sequences contained in the vectors. Nevertheless, in the interest of advancing prosecution, and not to concede the Examiner's position, the term "therapeutic gene" has been removed from all of the claims and replaced with the term "coding sequence of interest." Applicant expressly reserves the right to contest this grounds of rejection in a continuing application. Accordingly, Applicant respectfully requests that this rejection of claims 18-37 be withdrawn.

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As to claims 52-57 and 60, these claims have been cancelled to advance prosecution, rendering this rejection moot. As with the amended claims, however, Applicant does not intend for this to constitute a concession to the Examiner's position. Applicant expressly reserves the right to contest this grounds of rejection in a continuing application.

**Claim Rejections – 35 USC § 112, first paragraph (written description)**

Claims 10, 13, 23, 24, 26, 30, 31, 33, 35, 37, 44, and 47 have been rejected under 35 USC § 112, first paragraph, on the grounds that they contained subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant respectfully traverses and submits that the all of the unamended claims recite subject matter that is fully described in the specification.

In *The Regents of the Univ. of Calif. v. Eli Lilly & Co.* 43 USPQ2d 1398, the Court of Appeals for the Federal Circuit held that "an adequate written description of the a DNA ... requires a precise definition such as by structure, formula, chemical name or physical property" (citing *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993)). However, **information that is well known in the art need not be described in detail in the specification.** See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986).

As stated in the Office's *Written Description Guidelines* (66 Fed. Reg. 1099, 1103 (comment 24)): "The standard of 'conventional in the art' is supported by case law holding that a patent specification '**need not teach, and preferably omits, what is well known in the art.**' See *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534, 3 USPQ2d 1737, 1743 (Fed. Cir. 1987); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986). See also *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 1382, 53 USPQ2d 1225, 1231 (Fed. Cir. 1999)." (Emphasis added.)

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Here, the claimed invention, unlike the disputed invention in either *Eli Lilly* or *Fiers*, is directed not to a novel gene but to a novel, nonobvious arrangement of known genetic elements. DNA sequences encoding the proteins recited in claims 23, 24, 26, 30, 31, 33, 35, and 37 were well known in the art as of the filing date of this application. Likewise, the hTERT and osteocalcin promoters recited in claims 10, 13, 44, and 47 were well known in the art as of the filing date of this application. Thus, *Eli Lilly* and *Fiers* are inapposite to this case because the claim terms at issue here are not new or unknown biological materials that ordinary skilled artisans would miscomprehend. See *Amgen Inc. v. Hoechst Marion Roussel Inc.*, 65 USPQ2d 1385, 1398 (Fed. Cir. 2003).

Accordingly, Applicant respectfully submits that there can be no question that a person skilled in the art would have appreciated from the specification that the inventors had possession of the claimed invention at the time the application was filed. Nevertheless, in the interest of advancing prosecution, and not to concede the Examiner's position, the term "derived" has been eliminated from claims 10, 13, 44, and 47; the term "gene" has been replaced with "coding sequence" in claims 18-21, 29, and 36 to clarify Applicant's claimed invention. Applicant therefore respectfully requests that this rejection be withdrawn.

Claims 12, 15, and 46 have been rejected under 35 USC § 112, first paragraph, because the claimed vectors are allegedly not available. The Examiner suggested that this rejection could be overcome by depositing the vectors. In the interest of advancing prosecution, and not to concede the Examiner's position, these claims have been canceled. This cancellation is without prejudice or disclaimer, and Applicant expressly reserves the right to contest this grounds of rejection in a continuing application.

**Claim Rejections – 35 USC § 112, second paragraph**

Claims 4, 7, 10, 13, 22, 25, 27, 30, 31, 32, 34, 44, and 47 have been rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 7 was alleged to be unclear as to what "corresponding base pairs of other Adenovirus serotypes" encompasses. The Examiner queried whether Applicants mean the exact nucleotides 103-551 of other serotypes or a deletion of the functions of this region in other serotypes. In response, Applicant wishes to clarify that the latter is the intended meaning (deletion of the functions of this region in other serotypes). Moreover, Applicant respectfully submits that one of skill in the art would appreciate "corresponding" as meaning, in the context of the present invention, that when the nucleotide sequences of various adenoviral serotypes are aligned with each other, the base pairs "corresponding" to certain enumerated nucleotides of Ad5 are those that align with the enumerated Ad5 nucleotides, but that are not necessarily in these exact numerical positions in other serotypes. In this case, a deletion of nucleotides 103-551 of the Ad5 backbone will delete the native packaging signal; thus, a "corresponding" deletion in another serotype would delete that serotype's native packaging signal. Withdrawal of this rejection is therefore respectfully requested.

Claims 4, 10, 13, 44, and 47 were alleged to be indefinite for reciting "is derived from." In the interest of advancing prosecution, and not to concede the Examiner's position, the term "derived from" has been eliminated from these claims. Withdrawal of this rejection is therefore respectfully requested.

Claims 22, 25, 27, 30, 31, 32, and 34 were alleged to be indefinite in that the recited genes are not polypeptides. All of these claims have been amended to change "gene" to "coding sequence" and indicate that this coding sequence encodes the recited proteins. Withdrawal of this rejection is therefore respectfully requested.

#### New Claims

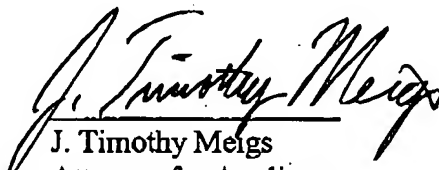
The Examiner indicated on page 11 of the Office Action that the invention distinguishes itself from the art by the inclusion of a termination signal following the left ITR. Applicant appreciates the Examiner's favorable assessment of the invention and has drafted several new claims (61-66) that recite this novel feature. Favorable consideration of new claims 61-66 is therefore respectfully requested.

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**Conclusion**

In view of the above amendments and remarks, it is respectfully submitted that the instant application is now ready for allowance. Early notice to this effect is now solicited. If any additional information is needed, the Examiner is invited to call Applicant's undersigned representative at (301) 258-4715.

Respectfully submitted,



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